

JP 16458

DOCKET NO.: C1039.70020US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Krieg et al.  
Serial No.: 09/337,584  
Confirmation No.: 9169  
Filed: June 21, 1999  
For: IMMUNOSTIMULATORY NUCLEIC ACID MOLECULES  
Examiner: Nita M. Minnifield  
Art Unit: 1645

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 26<sup>th</sup> day of October, 2004.

Kristin J. Ketelhut  
Kristin J. Ketelhut

MAIL STOP AMENDMENT

Commissioner For Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check in the amount of \$180 is enclosed to cover the filing fee. If the fee is insufficient, the balance may be charged to Deposit Account 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Krieg et al., Applicant*

By:

Helen C. Lockhart  
Helen C. Lockhart, Ph.D., Reg. No.: 39,248  
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Docket No.: C1039.70020US00  
Date: October 26 2004  
xNDDx



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Kristin J. Ketelhut

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**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180 as set forth in 37 C.F.R. §1.17(p) is enclosed.

836514.1

10/29/2004 SSITHIB1 00000166 09337584 180.00 0P  
01 FC:1806

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Docket No.</u>	<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>
*C1037.70050US01	10/952,254	September 27, 2004	Uhlmann et al.
*C1039.70020US01	10/921,086	August 18, 2004	Krieg et al.
*C1039.70048US11	10/928,762	August 26, 2004	Krieg et al.
C1040.70010US00	09/768,012	January 22, 2001	McCluskie et al.
*C1041.70005US02	10/894,655	July 16, 2004	Wagner et al.

\*a copy of this reference is not provided as the Office hereby waives the requirement under 37 CFR 1.98(a)(2)(iii) for submitting a copy of each cited U.S. patent application filed after June 30, 2003 and for applications filed before June 30, 2003, or that entered the national stage before June 30, 2003, if they are scanned to Image File Wrapper system and are available on Private PAIR.

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding International or Foreign National Application.

<u>Docket No.</u>	<u>Serial No.</u>	<u>Mailing Date</u>	<u>Type of Communication</u>
C1039.70054EP00	01202811.4	27 July 2004	European Search Report
C1039.70055EP00	01202813.0	28 July 2004	European Search Report
C1039.70056EP00	01202814.8	26 July 2004	European Search Report

The following are remarks concerning the other information cited:

**Comments Regarding Pending Interference No 105,171**

Applicants of the instant patent application are also named inventors on an issued patent US Patent No. 6,207,646 B1 which is currently involved in an Interference (Interference No. 836514.1

105,171). The instant patent application derives priority from US 6,207,646 B1. In view of the priority, Applicants have included on the attached 1449 a listing of the remainder of the motions filed in the Interference to date. Copies of the original preliminary motions were filed in the Information Disclosure Statement mailed to the Patent Office on August 25, 2004. Copies are enclosed for the Examiner's review. If the examiner would like any additional information on this subject she is encouraged to contact Applicants' representative at the number listed below.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

Serial No.: 09/337,584  
Conf. No.: 9169

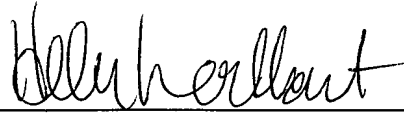
- 4 -

Art Unit: 1645

An early and favorable action is hereby requested.

Respectfully submitted,  
*Krieg et al., Applicant*

By:



Helen C. Lockhart, Ph.D., Reg. No. 39,248  
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600 Atlantic Avenue  
Boston, Massachusetts 02210-2206  
Telephone: (617) 646-8000

Docket No.: C1039.70020US00  
Date: October 28, 2004  
xNDDx

FORM PTO-1449/A and B (Modified)				APPLICATION NO.: 09/337,584	ATTY. DOCKET NO.: C1039.70020US00
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				FILING DATE: June 21, 1999	CONFIRMATION NO.: 9169
				APPLICANT: Krieg et al.	
				GROUP ART UNIT: 1645	EXAMINER: Nita M. Minnifield
Sheet	1	of	3		

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		2004-0142469	A1	Krieg et al.	07-22-2004
		2004-0143112	A1	Krieg et al.	07-22-2004
		2004-0147468	A1	Krieg et al.	07-29-2004
		2004-0152649	A1	Krieg	08-05-2004
		2004-0152656	A1	Krieg et al.	08-05-2004
		2004-0152657	A1	Krieg et al.	08-05-2004
		2004-0162258	A1	Krieg et al.	08-19-2004
		2004-0162262	A1	Krieg et al.	08-19-2004
		2004-0167089	A1	Krieg et al.	08-26-2004
		2004-0171150	A1	Krieg et al.	09-02-2004
		2004-0171571	A1	Krieg et al.	09-02-2004
		2004-0181045	A1	Krieg et al.	09-16-2004
		2004-0198688	A1	Krieg et al.	10-07-2004

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
		Patent Interference No. 105,171. Iowa Opposition 1 (opposition to motion to designate additional claims as corresponding to the Count) (Electronically filed, unsigned). September 9, 2004.		
		Patent Interference No. 105,171. Iowa Opposition 2 (opposition to motion for judgment based on lack of written description support and introducing new matter) (Electronically filed, unsigned). September 9, 2004.		
		Patent Interference No. 105,171. Iowa Opposition 3 (opposition to motion for judgment based on anticipation) (Electronically filed, unsigned). September 9, 2004.		
		Patent Interference No. 105,171. Iowa Opposition 4 (opposition to motion for judgment based on obviousness) (Electronically filed, unsigned). September 9, 2004.		
		Patent Interference No. 105,171. Iowa Opposition 5 (opposition to motion for judgment based on anticipation) (Electronically filed, unsigned). September 9, 2004.		
		Patent Interference No. 105,171. Iowa Opposition 6 (opposition to motion for judgment based on inequitable conduct) (Electronically filed, unsigned). September 9, 2004.		
		Patent Interference No. 105,171. Iowa Opposition 7 (opposition to motion for benefit of an earlier application under 7 CFR 1.633(j)) (Electronically filed, unsigned). September 9, 2004.		
		Patent Interference No. 105,171. Iowa Opposition 8 (opposition to motion to add additional claims under 37 CFR 1.633 (2) and (i)) (Electronically filed, unsigned). September 9, 2004.		
		Patent Interference No. 105,171. Regents of the University of California Opposition 3 (to Iowa Preliminary Motion 3 for judgment under 35 USC 135(b)). September 9, 2004.		
		Patent Interference No. 105,171. Regents of the University of California Opposition 4 (to Iowa Preliminary Motion 4 for judgment of no interference in fact). September 9, 2004.		
		Patent Interference No. 105,171. Regents of the University of California Opposition 5 (to Iowa Preliminary Motion 5 for judgment that UC's claim is not enabled). September 9, 2004.		
		Patent Interference No. 105,171. Regents of the University of California Opposition 6 (to Iowa Preliminary Motion 6 for judgment based on lack of adequate written description). September 9, 2004.		

FORM PTO-1449/A and B (Modified)		APPLICATION NO.: 09/337,584		ATTY. DOCKET NO.: C1039.70020US00	
OCT 28 2004		FILING DATE: June 21, 1999		CONFIRMATION NO.: 9169	
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		GROUP ART UNIT: 1645		EXAMINER: Nita M. Minnifield	
Sheet	2	of	3		

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

	Patent Interference No. 105,171. Regents of the University of California Opposition 7 (to Iowa Preliminary Motion 7 to redefine the interference). September 9, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Opposition 8 (to Iowa Preliminary Motion 8 to redefine the Count). September 9, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Response 9 (to Iowa Contingent Motion 9 for benefit). September 9, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Opposition 10 (to Iowa Contingent Motion 10 to redefine the interference). September 9, 2004.		
	Patent Interference No. 105,171. Iowa Reply 3 (in support of Iowa Preliminary Motion 3 for judgment under 35 U.S.C. §135(b)) (Electronically filed, unsigned). October 15, 2004.		
	Patent Interference No. 105,171. Iowa Reply 4 (in support of Iowa Preliminary Motion for judgment of no interference in fact) (Electronically filed, unsigned). October 15, 2004.		
	Patent Interference No. 105,171. Iowa Reply 5 (in support of Iowa Preliminary Motion 5 for judgment that UC's claim 205 is not enabled) (Electronically filed, unsigned). October 15, 2004.		
	Patent Interference No. 105,171. Iowa Reply 6 (in support of Iowa Preliminary Motion 6 for judgment based on lack of adequate written description) (Electronically filed, unsigned). October 15, 2004.		
	Patent Interference No. 105,171. Iowa Reply 7 (in support of Iowa Preliminary Motion 7 to redefine the interference) (Electronically filed, unsigned). October 15, 2004.		
	Patent Interference No. 105,171. Iowa Reply 8 (in support of Iowa Preliminary Motion 8 to redefine the count) (Electronically filed, unsigned). October 15, 2004.		
	Patent Interference No. 105,171. Iowa Reply 10 (in support of Iowa Preliminary Motion 10 to redefine the interference) (Electronically filed, unsigned). October 15, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Reply 1 (to Iowa's opposition to UC's motion to designate Iowa claims as corresponding to the Count). October 15, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Reply 2 (to Iowa's opposition to UC Preliminary Motion 2 for Judgment). October 15, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Reply 3 (to Iowa's Opposition to UC Preliminary Motion 3 for Judgment). October 15, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Reply 4 (to Iowa's Opposition to UC Preliminary Motion 4 for Judgment). October 15, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Reply 5 (to Iowa's Opposition to UC Preliminary Motion 5 for Judgment). October 15, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Reply 6 (to Iowa's opposition to UC Preliminary Motion 6 for judgment). October 15, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Reply 7 (to Iowa's Opposition to UC Preliminary Motion 7 for Benefit). October 15, 2004.		
	Patent Interference No. 105,171. Regents of the University of California Reply 8 (to Iowa's Opposition to UC Preliminary Motion 8 to add additional claims). October 15, 2004.		
	CAPRON et al., Immunologic aspects of schistosomiasis. Annu Rev Med. 1992;43:209-18. Review. Exhibit 2068.		
	RAZ et al., Potential role of immunostimulatory DNA sequences (ISS) in genetic immunization and autoimmunity. ACR Poster Session C: Cytokines and Inflammatory Mediators. 1996 Oct 20; Abstract Number 615.		
	SANTELIZ et al., Amb a 1-linked CpG oligodeoxynucleotides reverse established airway hyperresponsiveness in a murine model of asthma. J Allergy Clin Immunol. 2002 Mar;109(3):455-62. Exhibit 1041.		
	TOKUNGA, Response of the organism to DNA – With a focus on immunostimulatory DNA. Kansen Ensho Meneki. 2001 Autumn; 31(3): 1-12. Japanese. Exhibits 1048 and 1049.	Yes	

FORM PTO-1449/A and B (Modified)				APPLICATION NO.: 09/337,584	ATTY. DOCKET NO.: C1039.70020US00
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Sheet	3	of	3	GROUP ART UNIT: 1645	EXAMINER: Nita M. Minnifield

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

	VLASOV et al., Oligonucleotides in cells and in organisms: pharmacological considerations. <i>in</i> Prospects for Antisense Nucleic Acid Therapy of Cancer and AIDS. 1991: 243-66.		
	YAMAMOTO, Cytokine production inducing action of oligo DNA. Rinsho Meneki. 1997; 29(9): 1178-84. Japanese. Exhibits 1050, 1047, and 1046.		Yes
	[No Author Listed] DNA is the primary genetic material. <i>in</i> Recombinant DNA, Second Edition. Watson et al., editors. Scientific American Books, New York. p24-5, 147. Exhibit 1003.		
	[No Author Listed] Definitions. <i>in</i> The Dictionary of Immunology, Fourth Edition. Herbert et al., editors. Academic Press, 1995. p10. Exhibit 1004.		
	[No Author Listed] <a href="http://www.doctorfungus.com/the_fungi/Cryptococcus.htm">http://www.doctorfungus.com/the_fungi/Cryptococcus.htm</a> . Exhibit 1029.		
	[No Author Listed] <a href="http://www.doctorfungus.com/the_fungi/Blastomyces.htm">http://www.doctorfungus.com/the_fungi/Blastomyces.htm</a> . Exhibit 1030.		
	[No Author Listed] <a href="http://www.doctorfungus.com/the_fungi/Alternaria.htm">http://www.doctorfungus.com/the_fungi/Alternaria.htm</a> . Exhibit 1031.		
	[No Author Listed] <a href="http://www.cancer.gov/newscenter/pressreleases/cancervaccines/print">http://www.cancer.gov/newscenter/pressreleases/cancervaccines/print</a> . Exhibit 1042.		
	[No Author Listed] <a href="http://www.cancer.gov/clinicaltrials/learning/cancervaccines/print">http://www.cancer.gov/clinicaltrials/learning/cancervaccines/print</a> . Exhibit 1043.		
	[No Author Listed] Recombinant DNA Technology. <i>in</i> Molecular Biology of the Cell. Alberts et al., editors. Garland Publishing, Inc. 1983. Exhibit 2027.		
	[No Author Listed] Definitions. <i>in</i> Dorland's Illustrated Medical Dictionary, Twenty-sixth Edition. W.B. Saunders Company, 1981. Exhibit 2032.		
	[No Author Listed] Macromolecules in Prokaryotic and Eukaryotic Cells. <i>in</i> Molecular Cell Biology, Darnell et al, Editors. W.H. Freeman and Company, 1986. Exhibit 2033.		
	[No Author Listed] Definitions. <i>in</i> Immunology, Roitt et al., Editors. Gower Medical Publishing Company, 1985. Exhibit 2035.		
	[No Author Listed] Definitions. <i>in</i> Webster's New Collegiate Dictionary. The G&C Merriam Company, 1981. p287. Exhibit 2070.		
	[No Author Listed] <a href="http://www.cancer.org/docroot/ETO/content/ETO_1_4X_Cancer_Vaccines_Active_Specific_Immun_therapies.asp">http://www.cancer.org/docroot/ETO/content/ETO_1_4X_Cancer_Vaccines_Active_Specific_Immun_therapies.asp</a> . Exhibit 2072.		
	[No Author Listed] <a href="http://www.plwc.org/plwc/mainconstructor">http://www.plwc.org/plwc/mainconstructor</a> . Exhibit 2073.		
	[No Author Listed] <a href="http://www.icare.org/treatment/tcwwt4.htm">http://www.icare.org/treatment/tcwwt4.htm</a> . Exhibit 2074.		

EXAMINER:	DATE CONSIDERED:
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]